

Appl. No. 10/563,488
Amdt. Dated September 11, 2008
Reply to Office Action of June 11, 2008

Attorney Docket No. 81844.0049
Customer No.: 26021

Amendments to the Drawings:

Please delete Tables 1-5, originally submitted as drawing figures, from the drawings.

REMARKS

This application has been carefully reviewed in light of the Office Action dated June 11, 2008. Claims 1-5, 7-14 and 16-19 remain in this application. Claims 1 and 8 are the independent Claims. Claims 1 and 8 have been amended. Claims 6 and 15 are canceled without prejudice. It is believed that no new matter is involved in the amendments or arguments presented herein. Reconsideration and entrance of the amendment in the application are respectfully requested.

Drawing Objections

The drawing figures are objected to for including Tables 1-5 along with Figs. 1 and 2, but omitting Tables 1-5 from the Specification. In response, Applicant has amended the specification to include Tables 1-5 and deleted Tables 1-5 from the drawing figures. No new matter is introduced. Reconsideration and withdrawal of the above objection is respectfully requested.

Art-Based Rejections

Claims 1-3, 5-10 and 12-19 were rejected under 35 U.S.C. § 102(e) over U.S. Publication No. 2007/0134290 A1 (Rowland); Claims 4 and 11 were rejected under 35 U.S.C. § 103(a) over Rowland.

Applicant respectfully traverses the rejections and submits that the claims herein are patentable in light of the clarifying amendments above and the arguments below.

The Rowland Reference

Rowland is directed to a drug eluting medical device. A stent is coated with 500 μ g of a coating composition (*See, Rowland; Abstract and Example 3*).

The Claims are Patentable Over the Cited References

The present application is generally directed to a medical stent for in vivo placement in preventing or treating excessive vascular proliferation.

As defined by amended independent Claim 1, a stent for in vivo placement, the stent being formed in a substantially tubular shape and expandable in the outward radial direction of the substantially tubular shape. The stent contains a material nondegradable in vivo and a poly(lactide-co-glycolide) on at least a portion of the surface thereof. The weight of the poly (lactide-co-glycolide) being on the stent is 3 $\mu\text{g}/\text{mm}$ to 80 $\mu\text{g}/\text{mm}$ per unit length in the axial direction of the stent.

The applied references do not disclose or suggest the features of the present invention as defined by amended independent Claim 1. In particular, the applied references do not disclose or suggest, "the weight of the poly (lactide-co-glycolide) being on the stent is 3 $\mu\text{g}/\text{mm}$ to 80 $\mu\text{g}/\text{mm}$ per unit length in the axial direction of the stent," as required by the present invention.

Rowland discloses a stent coated with 500 μg of a coating composition without disclosure of a length of the stent. Page 2 of the Office Action cites Applicant's Examples 16-19 for disclosing a range of weights of poly(lactide-co-glycolide) (91 μg -1,040 μg per stent). Applicant's stent in the Examples has a length of 13 mm to thereby produce corresponding ratios of 7 $\mu\text{g}/\text{mm}$ - 80 $\mu\text{g}/\text{mm}$, which is the weight of poly(lactide-co-glycolide) per unit length. Importantly, since Rowland fails to disclose or suggest a length of the stent used for the 500 μg of matrix, the comparison of Applicant's weight per unit length value to Rowland's weight value to teach Applicant's claimed ratio is entirely speculative and does not teach each and every element of Applicant's claims. Although 500 μg is disclosed in Rowland, the determination of a corresponding ratio of μg to mm is impossible without a teaching in Rowland of a stent length. Since no such teaching is found, Rowland fails to disclose or suggest the ratio of the present invention.

In contrast, the present invention requires the weight of the poly (lactide-co-glycolide) being on the stent is 3 $\mu\text{g}/\text{mm}$ to 80 $\mu\text{g}/\text{mm}$ per unit length in the axial direction of the stent. This feature provides a stent for in vivo placement that reduces the rate of occurrence of stenosis or restenosis as compared to conventional stents (*See, Specification; Page 37, lines 20-28*). The amended claim range in particular provides a significant reduction in restenosis. For example, Examples 1-8 disclose weight per unit length in the axial direction of the stent between 3 $\mu\text{g}/\text{mm}$ and 80 $\mu\text{g}/\text{mm}$ while Examples 33 and 34 teach ratios of 1 $\mu\text{g}/\text{mm}$ and 100 $\mu\text{g}/\text{mm}$. As shown in Table 1, Examples 33 and 34 have restenosis rates of 63.1% and 58.4%, respectively, while Examples 1-8 all have rates below 50%, ranging from 40.7% to 48.1%. Thus, Applicant's claimed range of ratios performs particularly well.

Thus, Rowland does not disclose or suggest this feature of the present invention as required by amended independent Claim 1.

Since the applied references fail to disclose, teach or suggest the above features recited in amended independent Claim 1, those references cannot be said to anticipate nor render obvious the invention which is the subject matter of that claim.

Accordingly, amended independent Claim 1 is believed to be in condition for allowance and such allowance is respectfully requested.

Applicant respectfully submits that amended independent Claim 8 is allowable for at least the same reasons as discussed above with reference to amended independent Claim 1 and such allowance is respectfully requested.

The remaining claims depend either directly or indirectly from amended independent Claims 1 and 8 and recite additional features of the invention which are neither disclosed nor fairly suggested by the applied references and are therefore also believed to be in condition for allowance.

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Conclusion

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles, California telephone number (310) 785-4721 to discuss the steps necessary for placing the application in condition for allowance.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1314.

Respectfully submitted,
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Date: September 11, 2008

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